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PRINCIPAL INVESTIGATOR: Suzanne M. Miller, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

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Suzanne M. Miller, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

E-Mail: SM_MILLER@FCCC.EDU

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Breast cancer represents a serious health concern for women, across the disease spectrum. First, despite advances in technology used for intensive disease surveillance and innovative preventive options, interest in and utilization of these technologies is less than optimal, especially among low-income, African-American women and first-degree relatives. Second, among women who have completed cancer treatment, psychological after-effects that can have a negative impact on adjustment and adherence to screening practices are prevalent. Finally, for those cancer patients whose disease has metastasized, clinically relevant psychosocial adjustment problems need to be recognized and managed. It is for these reasons that research leading to improvements in quality of life throughout the disease spectrum is necessary. The Behavioral Center for Excellence, through the coordination of four projects, seeks to understand and evaluate psychosocial approaches for promoting psychological and physical adaptation to cancer risk, treatment and survival. Each project systematically assesses and addresses barriers to, and facilitators of, adjustment and adherence and evaluates interventions designed for this cause. With support from four core facilities, the BCE has assembled a multi-disciplinary research team to conduct an interrelated set of studies that are theoretically-guided, thematically convergent, and synergistic in the impact on the behavioral aspects of breast cancer.

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DOD Progress Report, Project I
Understanding Breast Cancer Risk Assessment and Screening Behaviors Among the Underserved

Suzanne M. Miller, Ph.D., Principal Investigator
Robert A. Schnoll, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Breast cancer represents a serious health issue for African American women. Higher morbidity and mortality rates in this population may be due, in part, to lower uptake of breast cancer risk assessment and genetic counseling programs, as well as lower adherence to breast cancer screening recommendations (Miller & Champion, 1997). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available breast cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the research team's Cognitive-Social Health Information-Processing (C-SHIP) model, the overarching goal of Project 1 is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and to adherence to breast cancer screening recommendations among African American women (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999). These data will be used to develop and pilot test an intervention program to boost enrollment in breast cancer risk assessment programs and increase adherence to breast cancer screening guidelines among African American women.

The specific aims for Project 1 are as follows:

Aim 1: To develop a psychosocial assessment instrument, tailored to low-income African American FDRs of breast cancer patients, which assesses key psychosocial predictors of breast cancer surveillance behaviors (*Phase 1*).

Aim 2: To evaluate the psychometric nature of this questionnaire and to identify key longitudinal predictors (e.g., fatalism, attentional style) of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations (*Phase 2*).

Aim 3: To examine the feasibility and short-term impact of a cognitive-social intervention that is designed from Phase 1 and 2 data (*Phase 3*). Feasibility variables include number of recruitment calls needed, recruitment and attrition rates, level of satisfaction with the intervention, and degree to which women would recommend the program to others. Impact variables will include intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

In Phase 1, we will conduct focus groups with African American FDRs of breast cancer patients (N = 30) to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. We expect that low monitoring as well as a pattern characterized by low levels of knowledge about genetic risk and assessment programs, inaccurate risk perceptions, high fatalistic beliefs, low pros and high cons about risk assessment, and extremely high levels of emotional distress will emerge as important correlates of program interest and screening adherence. Phase 2 will be a longitudinal study with African American FDRs of breast cancer patients (N = 100) to evaluate the psychometric nature of this instrument and to identify prospective psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence. We hypothesize that high monitoring, as well

as greater knowledge, higher risk perceptions, lower fatalism, higher pros and lower cons, and moderate levels of emotional distress will predict greater readiness to pursue risk assessment and higher levels of screening adherence. In Phase 3, we will examine the feasibility and impact of an intervention for African American FDRs of breast cancer patients (N = 30) on interest in breast cancer risk assessment and screening adherence. We hypothesize that 75% of FDRs approached will agree to participate and that there will be a 20% attrition rate. Further, FDRs receiving this intervention will demonstrate greater interest in risk assessment program, as well as greater screening adherence.

Study findings will have applicability to enhancing current cancer prevention and control initiatives with underserved populations. This study will: 1) provide a theory-guided instrument for identifying women less likely to pursue risk assessment and adhere with screening guidelines; 2) identify a feasible, evidence-based approach to motivating breast cancer screening and participation in risk assessment programs among traditionally underserved women; and 3) provide information concerning the need for the simultaneous targeting and tailoring of interventions to promote decision-making about breast cancer assessment and adherence to surveillance behaviors. Overall, this study will provide important data for implementing breast cancer health-promotion interventions among underserved women on a broader scale.

BODY

During Year 1, we anticipated accomplishing Task 1 and initiating Task 2, as outlined in our Statement of Work. Task 1 involved refining a psychosocial familial risk questionnaire, tailored to low-income African American FDRs of breast cancer patients, that assesses key psychosocial correlates of interest in breast cancer risk assessment programs and adherence to breast cancer screening guidelines (*Phase 1*). We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards	(Month 1)
b. Recruit Focus Group Participants for Phase 1	(Months 2-3)
c. Conduct Focus Groups	(Month 4)
d. Analyze Focus Group Data	(Month 5)
e. Develop Assessment Instrument for Phase 2	(Month 6)

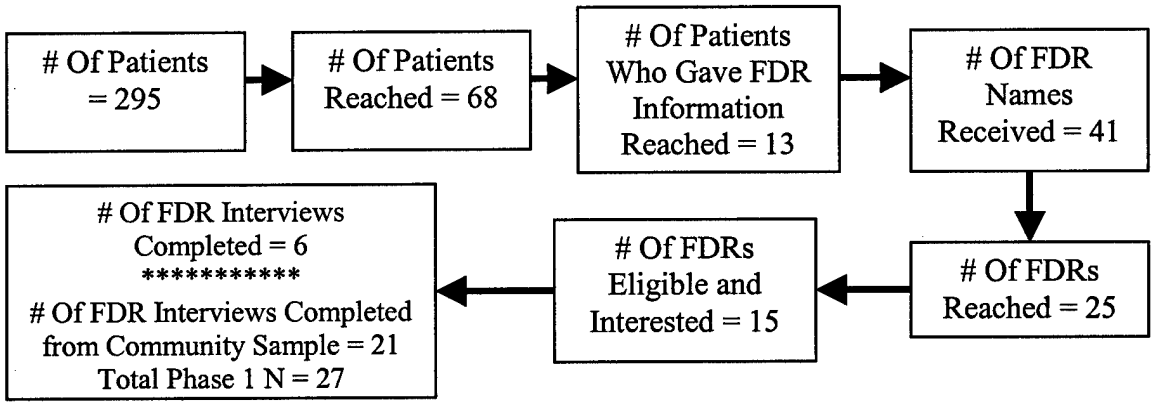
Task 2 involved evaluating the psychometric nature of the psychosocial familial risk questionnaire and identifying key longitudinal predictors of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations among female African American FDRs of breast cancer patients (N = 100; *Phase 2*). We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards	(Month 7)
b. Establish Recruitment Procedures/Staff Training for Phase 2	(Month 8)
c. Recruit Participants, Conduct Longitudinal Study	(Months 9-30)

To date, we have completed *Phase 1* of the overall project (i.e., Task 1, a-e). We have also submitted the protocol for *Phase 2* to the FCCC IRB for review (i.e., task 2, a) and expect to begin *Phase 2* data collection in the fall of 2003. We still may complete Task 2 by the pre-stated completion date of Month 30.

There are several reasons that account for Task 1 taking more time than expected to complete. First, since this project involves the recruitment of study participants from outside of Fox Chase Cancer Center, we had an additional Institutional Review Board (IRB) from which to seek approval before initiating participant recruitment. In addition, we had not figured the amount of time needed for securing DoD IRB review into our calculations. Thus, rather than taking the allotted 1 month for IRB approval of the protocol, at least 4 months were needed before we could initiate participant recruitment. Second, our projected accrual of the target population has been slower than expected because it has been a challenge to reach African American breast cancer patients. Our initial recruitment strategy involved receipt of a patient list, including phone numbers, from our physician-collaborators at Temple University Hospital. A Research Assistant (RA) would then attempt to contact these patients to seek contact information about the patients' first-degree relatives (FDRs). Once FDR contact information was gathered, the RA would attempt to contact the FDR to assess eligibility and interest in the study. Below, in Figure 1, we summarize our efforts to date using this recruitment approach.

Figure 1: Summary of Recruitment Efforts



Based on these data, we were only able to reach about one-quarter of the patients because of incorrect telephone numbers, changed telephone numbers that were not listed, or because the telephone calls were never answered, even after upwards of 20 attempts. Thus, we amended the study to allow trained Health Educators and RAs to attend clinic where new patients were receiving care. The goal was to reach a greater proportion of patients by providing all African American patients with a study brochure and making study personnel available each day to collect FDR information. Unfortunately, since this amendment was approved, there has not been a significant change in recruitment. Our sense is that patients remain wary of providing FDR information to the Fox Chase Cancer Center personnel for reasons of mistrust or skepticism, since they are not well integrated into the Temple team. Therefore, we initiated a partnership with local churches and area

residential communities in order to increase recruitment. We were able to recruit 21 women through these community-based recruitment strategies and, thus, complete recruitment for *Phase 1*.

We have analyzed the qualitative data from Phase 1 and identified specific themes concerning breast cancer screening and genetic testing among African American FDRs of breast cancer patients and survivors. Three independent coders analyzed the transcripts and formed frequency distributions to represent common responses across the sample. The findings are discussed below, but it is important to note that the assessment instrument to be used for Phase 2 was substantially revised based on the findings ascertained from Phase 1.

Overall, we believe that our recruitment difficulties stemmed from an inability to gain access to the FDR information. Therefore, we plan to work with community-based organizations in order to recruit for subsequent phases of this study.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Completed collection of focus group data (Phase 1).
- Met with the Communications Core to develop focus group materials and protocol.
- Met with Informatics Core to discuss Project data issues.
- Trained staff at Temple University Hospital.
- Developed extensive recruitment procedures.
- Devised new recruitment procedures that integrated Temple University Hospital Physicians into the recruitment process by having them introduce the study to their patients and thereby facilitate the understanding of the study.
- Devised recruitment procedures involving community-based sites.

REPORTABLE OUTCOMES

Overall, there was high concordance among the three transcript reviewers. While we are currently preparing a manuscript to describe Phase 1 procedures and results, we can offer the following summary.

- About 1/3 of women indicated that genes influenced risk for breast cancer;

- Few women – about 10% - recognized that reproductive history influenced breast cancer risk;

- 10% of women indicated that smoking increases breast cancer risk;

- Only about 19% of women recognized that their family history increased their risk for breast cancer;

- 1/4-1/3 of women cited the following as barriers to screening and genetic testing: lack of knowledge, fear and emotional distress, concern of finances or insurance coverage, and pain or physical discomfort;

- About 50% of women were able to identify mammography, breast self-exam, and clinical breast exam as methods for breast cancer screening, yet virtually the entire sample new little about the procedures involved in breast cancer genetic testing;

- Only about 1/4 of women showed strong positive attitudes about breast cancer screening and familial risk assessment;

- About 1/3 of the sample indicated that they wished they had more information about both breast screening and familial risk assessment and expressed strong wishes for healthcare providers to provide community outreach programs to meet this objective.

Below is a list of presentations and publications that are related to Project 1 activities.

- Presentations:

  Fleisher, L., Schnoll, R., Miller, S., McKeown-Conn, N., Brower, L. Annual Meeting of the American Society of Preventive Oncology. Poster on: Women's self-reported knowledge about cancer risks, risk assessment programs and genetic testing: Preliminary findings. New York, N.Y., March, 2001.

  Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., Babb, J. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Increasing Knowledge of Cancer Risk and Cancer Programs. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Orlando, FL, September, 2002.

Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

- Publications:

Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (2001). Tailoring psychosocial interventions to the individual's health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Andersen (Eds.), Psychosocial interventions in cancer. Washington D.C.: American Psychological Association.

Miller, S.M., Sherman, K., Buzaglo, J., & Rodoletz, M. (2001) Monitoring-Blunting behavioral signatures in coping with health threats: The example of cancer. Psicologia della Salute, 3, 37-48.

Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Sherman, K.S., Miller, S.M., Sheinfeld-Gorin, S. (in press) Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington, D.C.: American Psychological Association, in preparation.

Miller, S.M. McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Overall, we have successfully completed Phase 1 of this project, namely the focus group interviews with 27 participants. We conducted qualitative analyses with the data gathered from this sample and identified specific themes that, in turn, guided our refinement of an assessment instrument to be used in *Phase 2* of this study. At this point, we have refined the assessment instrument and are currently working to secure IRB approval for *Phase 2* of the study. We anticipate beginning *Phase 2* in September or October 2003. We acknowledge that we are about 6-7 months behind schedule for Project 1, largely due to unanticipated delays from seeking additional regulatory approvals from the recruitment

site and from the DoD, and from practical difficulties reaching the patient population from whom we are trying to recruit FDRs.

Nevertheless, we have gained a better understanding of the possible reasons why recruitment has been slower than anticipated. Further, we have taken steps to increase the rate of successful contact of patients (e.g., sending research personnel to the clinics) and established the necessary contacts for acquiring a community sample. These modifications enabled us to successfully complete *Phase 1* of the study and will facilitate completion of *Phase 2*. We expect that these modifications to our recruitment procedures will allow us to achieve our recruitment goals with this uniquely challenging, and understudied, population and successfully complete the entire study as proposed.

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Miller, A.M., & Champion, V.L. (1996). Mammography in older women: one-time and three-year adherence to guidelines. Nurs Res, 45(4), 239-245.

Miller, S. M. (1995). Monitoring versus blunting styles of coping with cancer influence the information patients want and need about their disease. Implications for cancer screening and management. Cancer, 76(2), 167-77.

Miller, S. M. (1996b). Monitoring and blunting of threatening information: Cognitive interference and facilitation in the coping process. In I. G. Sarason, Pierce, G.R., & Sarason, B.R. (Ed.), Cognitive Interference: Theories, methods, and findings. (pp. 175-190). NJ: Lawrence Erlbaum.

Miller, S.M., Fang, C.Y., Manne, S.L., Engstrom, P.E., Daly, M.B. (1999). Decision making about prophylactic oophorectomy among at-risk women: Psychological influences and implications. Gynecologic Oncology, 75, 406-412.

Miller, S.M., Shoda, Y., & Hurley, K. (1996). Applying cognitive-social theory to health-productive behavior: Breast self-examination in cancer screening. Psychological Bulletin, 119, 70-94.

DOD Progress Report, Project II
A Teachable Moment within the Family: From Concept to Community

Mary B. Daly, MD, Principal Investigator
Dr. Suzanne M. Miller, Ph.D., Co-Investigator
Samuel Litwin, Ph.D., Statistician

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Despite advances in cancer detection and treatment, breast cancer remains the most common cancer among women and accounts for a staggering number of lives lost per year. Knowledge about both the genetic and environmental causes of breast cancer is being translated into tailored screening protocols, chemoprevention approaches, and diet and lifestyle modifications, targeted to women at highest risk. First-degree relatives (FDRs) of breast cancer patients comprise a particularly appropriate group among whom to concentrate efforts to maximize risk reduction and early detection. Although a family history of breast cancer is a well-known risk factor, studies have shown that many women are unsure of their risk status and are often unaware of the cancer prevention strategies that may be appropriate for them. The diagnosis of breast cancer in a close relative may provide the ideal opportunity, a "teachable moment," to reach at-risk family members to address their needs and concerns and make available risk assessment and counseling programs. The goals of the proposed study are to test a health communication message personalized to a set of demographic, clinical and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attendant to the recent diagnosis in an FDR. The project represents a partnership between a comprehensive cancer center (FCCC) and a series of community hospitals (FCCC Network affiliated sites) in an effort to enhance dissemination of state-of-the-art cancer prevention and control strategies to the community setting. Affected patients identify at-risk relatives at each site, and permission is sought to contact them by phone for participation in the study. Study participants are randomized to either a personalized message keyed to age, risk level, family history, screening behaviors and attention style, or to a general, non-personalized health message. Surveys are administered to adult daughters and sisters at two time points -- baseline and 12 months later -- in order to capture both newly formed intentions to seek cancer risk information and counseling, adopt lifestyle changes, and/or initiate appropriate surveillance regimens, and the actual action upon these intentions. The C-SHIP model of cognitive-affective processing of health threats is used as the theoretical framework for this study.

Aim 1: To develop and evaluate a theory-driven message tailored to a set of relevant variables including monitoring attentional style to enhance participation in FCCC's Family Risk Assessment Program (FRAP). The hypotheses are that patients exposed to this tailored message will be more likely to 1) seek risk assessment and counseling through FRAP, and 2) adopt risk-reducing behaviors than those patients who receive a non-tailored risk message.

Aim 2: To examine the moderating effects of individual differences in educational level, relationship to the patient, and level of anxiety and cancer-related distress.

BODY

FCCC IRB and DOD approval for amendment #4/DoD#1 was received during this period. This amendment covered revised language in both the patient and relative

informed consent forms to clarify that subjects' records may be inspected and/or photocopied by the Department of Defense. Additionally, a study-specific HIPAA authorization form was approved by the FCCC IRB and implemented with patients and relatives recruited to the study beginning April 14, 2003. The focus during the past year has been recruitment of participants and capture of data, as well as the creation of tailored print materials. The print materials are distributed to participants in both study groups as follow up to their telephone counseling session. Fact sheets were designed to reinforce the information covered in the telephone counseling sessions. A series of 10 tailored fact sheets was developed to correspond to the variables used in those participants randomized to the tailored intervention group (e.g. level of family/personal risk factors, current compliance with breast cancer screening). Each participant in this group receives a package with two tailored fact sheets and one "Personal Risk Profile" which elaborates on the subject's risk for breast cancer as calculated using the Gail Model. Additionally, an exercise and diet fact sheet was developed for use with the non-tailored (i.e. control) group. Follow up print materials are sent to study participants within 2 weeks of their telephone counseling session. In addition to the materials we have developed, applicable print materials from the National Cancer Institute, and the Family Risk Assessment Program brochure are included in the print material packets. One FCCC Network Hospital (Reading Hospital) has the study approved at their site and ongoing reviews continue. Discussions with additional FCCC Network and affiliated hospitals continue (Virtua Health, Geisinger Medical Center, ChristianaCare Health System, Polyclinic Hospital and Paoli Memorial Hospital) and the sites are at various stages of obtaining IRB approval to conduct the study at their institutions. The following is a description of the research accomplishments associated with each Task as outlined in the approved Statement of Work.

During Year 2, we completed Task 1, the study start-up phase. We subdivided this task into the following sub-tasks:

a.	Communications core to create tailored, personalized messages for experimental intervention	(months 1-6)
b.	Finalization of survey instruments	(months 1-3)
c.	Finalization of recruitment strategies	(months 1-3)
d.	Training of study personnel	(months 4-6)

The study staff and Communications Core developed the tailored intervention and control group scripts with corresponding print materials. The study team and Communications Core met on a regular basis to complete the development of the message library and tailored print materials.

The 12-month follow up Health History Questionnaire is being revised to capture additional information at this time point. Study staff has met with the Informatics Core on a regular basis to facilitate programming requirements enabling participant data capture and project timeline management.

Recruitment strategies were implemented at FCCC and continued in planning stages at the Network sites. After a staff in-service conducted by the Project Manager, the recruitment brochure was put into circulation through the Breast Evaluation Clinic at FCCC. All newly diagnosed breast cancer patients are provided with a study brochure at their initial visit and clinic nurses describe the study to patients so they can consider contacting study staff or informing their FDRs, at the appropriate time after their diagnosis.

The Project Manager and Research Assistant incorporated the FCCC Health Information Management System into recruiting processes. Additional recruitment strategies were put in place including utilization of clinic schedules of breast cancer patients new to FCCC. The Project Manager continued meeting with the study staff at FCCC Network and affiliated hospitals to facilitate approval of the study, and to explore appropriate recruitment strategies at each site. Training of the Health Educators who are conducting the telephone counseling sessions was completed. The study team has met on an ongoing basis to identify problems, develop support tools and streamline the scheduling and implementation of the counseling sessions. A list of frequently asked questions (FAQs) and answers was developed to aid the counselors during their sessions with study participants.

To date, the DoD and FCCC IRB have approved all amendments. Four additional sites continue to plan for submissions to their respective IRBs. Finally, a poster was presented at the annual meeting of the American Public Health Association November, 2002.

During Year 1 we implemented items a.-h. of Task 2, Conducting a Prospective, Randomized Trial. This task was also subdivided into sub-tasks that will be completed over a number of months:

a.	Identification of FDRs	(months 7-30)
b.	Mailing of pre-call letter	(months 7-30)
c.	Baseline telephone interview	(months 7-30)
d.	Follow-up letter	(months 7-30)
e.	Delivery of experimental and control sessions	(months 8-31)
f.	Quality control tests performed on a randomized sample of sessions	(months 8-31)
g.	Follow up print materials mailed to participants	(months 8-31)
h.	Informatics Core to complete data entry and management	(months 7-44)
i.	Conduct 12-month follow up phone call	(months 20-44)

Identification of FDRs for recruitment to the study began during the past year. Current breast cancer patients are approached during their clinic/physician visits at FCCC in order to describe the study and obtain their permission to contact their relatives. Informed consent is obtained through completion of the Patient Informed Consent form and after April 14, 2003, the HIPAA form "Authorization for Use and Disclosure of Protected Health Information for Research Approved by Fox Chase Cancer Center (IRB)". Patients

are then mailed a copy of these signed forms for their records. As mentioned above study staff worked with Breast Evaluation Clinic staff at FCCC (and site staff at their respective facilities) to identify patients at the appropriate time during their treatment (i.e. 6-12 months following diagnosis). In addition to including them in all new breast cancer patient information packets, participant brochures have been placed at various places within FCCC to generate interest among eligible FDRs who may be accompanying their mother/sister during an appointment. Finally, in-service presentations were made to various internal FCCC departments (e.g. FCCC hospice program) and community-based professional meetings (e.g. nursing staff of Samaritan Hospice in New Jersey).

The processes associated with generating and mailing the pre-call letters was implemented collaboratively between study staff and the Informatics Core. The letter has been programmed by the Informatics Core and is being generated for eligible FDRs identified by study staff. The study staff mails the pre-call letter with the Relative Informed Consent and HIPAA forms. A project management/timeline contact log is generated by data management that flags the date which study staff can begin to contact the FDR if they have not previously called to opt out of the study within the time specified in the letter. Study staff then contacts the potential participant (FDR) to discuss the study and review the Relative Informed Consent and HIPAA forms. If FDRs agree to participate in the study, they are asked to sign and return the informed consent and HIPAA forms. They are also asked the best day and time to contact them so that the baseline interview can be conducted once the signed consent form is received at FCCC. Photocopies of the signed informed consent and HIPAA forms are then sent to the FDRs for their records

The baseline instrument has been programmed by the Informatics Core to enable capture of data during the initial participant telephone interview. Specific questions from the instrument were identified to guide the tailoring of messages for the individuals in the experimental group. This instrument is administered at the baseline telephone interview once signed Relative Informed Consent and HIPAA forms are received at FCCC.

The Informatics Core staff has programmed the follow-up letter. Once the baseline interview has been conducted and data are entered into the database, the Informatics Core generates the follow up letter and provides it to the study staff. This letter thanks subjects for their participation in the study and confirms the date and time of their upcoming telephone counseling session. The monetary reimbursement is enclosed and the letter is mailed by study staff to each participant.

The tailored message library was finalized in collaboration with the Communications Core. Delivery of telephone counseling sessions began during this period. Individuals randomized to the experimental group have messages tailored first to their attention style (high vs. low monitor), then to the individual variables (e.g. calculated risk-high vs. intermediate risk; screening behaviors-complier vs. non-complier). The control group receives a general health message that has been used in previous studies with the same subject population. The counseling sessions take 20-30 minutes to complete and conclude with a description of the FRAP program and instructions on how to become enrolled. The

Project Manager worked closely with the Informatics Core to establish an algorithm for programming the tailoring system so that an individualized script is printed for each study participant. The control group script was finalized and programmed so that a personalized script is produced for each participant in the control group, identifying their affected relatives and inviting them to participate in a local FRAP, either at FCCC or a Network hospital depending on where they live.

The tailored follow up print materials for use with the experimental group were developed during this period in tandem with the tailored message library. Within a week of the counseling phone call each experimental group participant receives a copy of tailored print materials designed by the study staff and Communications Core which reinforce the messages delivered by phone. Also included is an invitation to attend the FRAP for more in depth education and personal counseling about their risk for breast cancer. The tailored print materials are in the form of fact sheets and each experimental group participant receives two: 1) Family History/Risk Factors, and 2) Screening Recommendations. In addition, each individual in the experimental group receives a Personal Risk Profile describing their calculated level of risk as determined by the Gail Model (see Appendix A). The control group participants receive a packet that includes a general Diet and Exercise fact sheet developed by the study staff and Communications Core. Also included in the control group packet are NCI brochures on diet and breast cancer screening, (e.g. *"Time to Take Five: Eat 5 Fruits and Vegetables a Day" and "Mammograms: Not Just Once, But for a Lifetime"*). Participants in both groups also receive a FRAP brochure and an invitation to attend the FRAP Program for more in depth education and personal counseling about their risk for breast cancer.

Telephone counseling sessions are being taped and monitored for quality control on a subset of participants who previously gave permission to be audio taped.

As noted above, the Informatics Core has completed the programming required to enter the baseline interview data. Additionally, a tracking system has been established in order to facilitate efficient management of the study. This system utilizes a checklist and data entry process to track each study event as it is completed and enables the study team to identify reasons for participant's declining/terminating. Data entry is conducted on an ongoing basis as each participant enrolls in, and completes each step of the study. Informatics Core staff enters dates of informed consent and HIPAA authorization received on each participant. They also enter data from the baseline questionnaire as each telephone interview is completed. The Research Assistant enters all checklist activity into a program developed by the Core. Additionally, all appointments are scheduled and managed utilizing an MS Outlook calendar.

The 12-month follow up data collection instrument is being revised to reflect the capture of additional items of interest to the study team.

Task 3, to conduct data analyses on all data collected and to present/publish findings is not applicable to the Year 2 Report. However, the subtasks are as follows:

a.	Statistical analyses of data obtained	(months 40-46)
b.	Publicize study findings	(months 43-48)
c.	Prepare final report for granting agency	(months 46-48)

KEY RESEARCH ACCOMPLISHMENTS

- Obtained informed consent on 60 subjects and completed telephone counseling sessions with 45 subjects.
- Attend and participate in monthly Center meetings.
- With the Communications Core, study staff completed development of tailored message library and corresponding print materials.
- Implemented recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives.
- Finalized telephone counseling scripts for both study groups and worked with Informatics Core staff to produce personalized scripts for each participant.
- Ongoing communication with FCCC Network site staff (N=5) to coordinate study approval and start up activities at each site.

REPORTABLE OUTCOMES

- Presentations

  A poster presentation was made at the annual meeting of the American Public Health Association in November, 2002. The poster focused on the process of developing the tailored communication messages.

  > Ross, B.S. & Daly, M.B. Cancer—A Teachable Moment Within the Family: From Concept to Community. American Public Health Association Annual Meeting. Poster presentation. Philadelphia, PA November, 2002.

CONCLUSION

Subject recruitment began during the past year. The development of tailored messages library and corresponding tailored print materials was completed in collaboration with the Communications Core. We will continue to utilize the established recruitment procedures and have developed an internal queue of women who will be at the appropriate time from diagnosis (e.g. 6-12 months) at each month in the future so that we have a steady flow of

potential subjects to approach for participation in the study. Approval at the Network sites has been slower than anticipated and is driven in large part by the fact that they do not have dedicated staff to recruit participants. However, now that we have begun recruiting at FCCC and have identified and implemented successful recruitment procedures, we will continue to work with the sites to identify the best ways to approach the study and anticipate that 2-3 sites will receive IRB and subsequent DoD approval so that they can begin recruiting in the coming year.

REFERENCES

None

DOD Progress Report, Project III
Facilitating Re-entry Following Treatment for Primary Breast Cancer

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Dr. Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator
Dr. Lori J. Goldstein, MD, Co-Investigator
Dr. Mary Cianfrocca, MD, Co-Investigator

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

As screening and surveillance for breast cancer has increased and treatment improved, the number of survivors of primary breast cancer has increased substantially (ACS, 2000; Pandey et al., 2000). The 5-year relative survival rate for localized breast cancer has increased from 72% in the 1940s to 96% today (ACS, 2000). Further, 71% of women diagnosed with breast cancer survive 10 years, and 57% survive 15 years (ACS, 2000). As the number of cancer survivors has increased, so too has the concern for the psychosocial adaptation of cancer survivors (e.g., Andersen, 1994; Ganz et al., 1996; Ganz et al., 1998; Gotay & Muraoka, 1998; Kornblith, 1998; Kurtz, Wyatt, & Kurtz, 1995; Schag et al., 1993; Wyatt & Friedman, 1996; Weitzner et al., 1997). However, little research has focused on easing the transition of individuals with early stage breast cancer from active treatment to follow-up care, referred to as the re-entry phase; even less research has focused on how individual differences moderate the process of adjustment to the challenges of survivorship (see Andersen, 1994; Helgeson et al., 2000). Guided by the Cognitive-Social Health Information Processing model (Miller, Shoda, et al. 1996; Miller, Mischel, et al. 1996), the primary objective of the proposed study is to develop and evaluate a tailored Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry following adjuvant treatment for primary breast cancer (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999).

The specific aims for Project 1 are as follows:

Aim 1: To develop and evaluate a theory-based, individually tailored Cognitive-Affective Processing (CAP) intervention to facilitate re-entry following adjuvant treatment for primary breast cancer.

Aim 2: To examine the moderating effects of individual differences in attentional style (i.e., high vs. low monitoring) on the impact of the proposed intervention.

To reach the primary objective of the proposed study, four focus groups will be conducted during Phase I of the study (months 1-6). Eight to ten women (N=40) from the target population (early stage, primary breast cancer patients) will participate in the focus groups. The goal of the focus groups is to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups will be designed to explore and assess the challenges confronted by the study population during the transition from being an active patient in treatment to a breast cancer survivor, i.e., the 're-entry' phase. Specifically, focus group participants will be asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas to be targeted include their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information will be used to further refine the intervention and measures. The final two focus groups will be designed to evaluate the intervention and the battery of measures, for their applicability and feasibility. Focus group participants will review, and make suggestions about, both the

proposed intervention and battery of measures. All focus groups will be conducted by the Communications Core and focus group data will also be analyzed by the Core.

During Phase II, women (N=300) who have been diagnosed with Stage 0, I, or II breast cancer and are being treated at Fox Chase Cancer Center (FCCC) will be contacted for participation. Potential participants will be identified through the scheduling office at the Breast Cancer Evaluation Clinic at FCCC and will be recruited near the completion of their adjuvant treatment. After they have been given a description of the study, participants who meet eligibility criteria and wish to participate will be asked to sign a consent form. Consenting participants will be stratified according to treatment type (chemotherapy vs. radiation vs. both); patients in each of the three strata will be randomized into either the intervention or control condition. All consenting participants will receive the intervention or control session during their first post-adjuvant treatment follow-up medical visit. A booster session will be given two-week post-counseling intervention. All participants will be assessed via mail at three, six and twelve months-post-intervention. The health educator will contact the participant by phone to collect follow-up data in the event that participants do not return the questionnaires within 2 weeks.

BODY

During Year 1, the plan was to complete Task 1 and initiate Task 2, as outlined in our Statement of Work. Task 1 involves coordinating with the Communications Core in the testing and subsequent refinement of the cognitive-affective intervention designed to facilitate "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. This was to be accomplished through the use of focus groups to test both the intervention and the measures, with the Communications Core leading the process. The specific aims of Task 1 are to:

a.	Recruit Focus Group Participants for Phase I	(Month 1-2)
b.	Conduct Focus Groups	(Months 2-3)
c.	Analyze Focus Group Data	(Month 3-4)
d.	Refine Interventions/Measures	(Month 4-5)
e.	Conduct Focus Groups to Evaluate Refined Interventions/Measures	(Month 5)
f.	Establish Recruitment Procedures/Staff Training	(Months 5-6)

Phase I implementation is currently underway. In October 2002, recruitment for the four focus groups officially began. In cooperation with the Breast Evaluation Center (BEC) at FCCC 286 medical record numbers of potentially eligible participants were obtained from the nursing coordinator. Using the Hospital Information Management System (HIMS), FCCC's electronic patient information database, the medical history of the 286 patients was reviewed to determine eligibility. Of these 286 patients, 71 women were found to be eligible for participation in the focus groups. Three focus groups were scheduled between November 2002 and February 2003. Of the 71 women found eligible,

54 were successfully contacted. After multiple calls at various times throughout the day, 17 patients were unable to be contacted to solicit participation before the scheduled focus groups. Of the 54 patients that were contacted 27 agreed to participate in one of the upcoming focus groups. The 27 participants that declined participation cited reasons that included: lack of interest (41%), time constraints/conflict with work (33%), do not drive (11%), living out of state (7%), too far to travel (4%), and too much extra effort with current cancer treatment (4%). Out of 27 participants who initially agreed to participate, 6 called to cancel before the scheduled focus group and 5 did not show up without calling to cancel, leaving 18 who attended. The majority of the participants in the focus groups were diagnosed with Stage I breast cancer (56%). 39% were diagnosed with Stage II breast cancer (71% Stage IIA and 29% Stage IIB), and 1 patient was diagnosed with Stage I in the left breast and Stage IIA in the right breast. 50% of the participants had undergone a lumpectomy, 19% had undergone a mastectomy, 16% had undergone a lumpectomy and a mastectomy, and 10% had undergone a lumpectomy and a lymph node dissection. One participant (5%) had neither a lumpectomy nor a mastectomy, but rather had a lymph node dissection. 67% of the participants had received chemotherapy and radiation therapy, 28% had chemotherapy alone, and 5% had radiation therapy alone.

By February 2003, three focus groups were completed. Members of the research team transcribed the tapes from the three focus groups, which were then coded and analyzed to identify specific themes regarding concerns and issues of women as they complete treatment for primary breast cancer. The responses from the focus groups were coded according to the five cognitive-affective mediating units of C-SHIP (i.e., Self-Construals (e.g., fear of recurrence, metastasis, end of regular check-ups with doctors); Expectancies (e.g., time frame for hair re-growth, lingering pain from radiation, fatigue); Values/Goals (e.g., concerns for other female relatives particularly in the absence of prior family history, body image and sexuality concerns); Affect (e.g., relief, worry, anger); Self-Regulation (e.g., diet, personal action to reduce side-effects)). Specific responses from the focus groups are described below. These responses are guiding the development of the Phase II intervention.

In December 2002, a meeting was held with BCE project and core leaders and the External Advisory Committee. The purpose of this meeting was to discuss the status of each project and core and to obtain valuable feedback from the external advisors. The main findings from Project 3 focus groups were discussed and suggestions were made for the development of the intervention regarding the most effective mode of delivery (i.e., telephone vs. in-person) and intensity/frequency of intervention sessions, the optimal time following completion of treatment for delivery of the intervention, and the most appropriate focus of the intervention. The input and advice obtained from the advisory committee is being considered as the Phase II intervention is developed.

In addition to the suggestions of the external advisors, the responses obtained from the focus groups are being used to refine the barriers intervention. While the intervention will address the cognitive-affective mediating units of the participants, there is now a better sense of understanding of the primary concerns and issues of breasts cancer survivors as well as the barriers to re-entry, which will be personally assessed prior to the

intervention session and thoroughly addressed in the intervention session, giving particular attention to participants' preferences for the timing of the delivery of the counseling intervention and the method by which the intervention will be delivered. The intervention draws from the NCI publication, Facing Forward, and is consistent with its philosophy of taking an active role in recovery in combination with accepting changes that are beyond the patient's control. Further, the intervention will provide strategies for coping with barriers to the re-entry phase of recovery and participants will receive additional resources for dealing with their concerns.

Two more focus groups will be scheduled upon completion of the intervention. The last two focus groups will be designed to evaluate both the initial assessment and the intervention for their thoroughness, applicability and feasibility. This will be a cost- and time-efficient way to enhance the tailoring of the intervention to the specific needs of the participants in that focus group participants will be given the opportunity to make suggestions on any issues that they feel are not adequately addressed.

Project meetings are held on a regular basis with the Communications Core to discuss findings of Phase 1 focus groups as well as to evaluate the intervention as it is developed. Particular attention is being give to the responses from the focus group participants to adequately address the most frequently cited concerns and issues relating to the completion of adjuvant therapy.

Task 2, which was to be initiated during year 1 and continued into year 3, involves conducting a randomized trial (N=300) comparing the Cognitive-Affective Processing (CAP) protocol designed to address the barriers to "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. The CAP intervention will be compared with a General Health Education (GHE) control to equate for time and attention. The specific aspects of Task 2 are to:

a.	Recruit Participants, Randomize to Treatments, Test Interventions	(Months 7-30)
b.	Participants Eligible for Genetic Testing will be Referred to the Genetic Susceptibility Testing Laboratory Core	(Months 7-30)

Task 2 will begin once the intervention has been redesigned and approved by the IRB.

Our team has attended consultation meetings with the Informatics Core to initiate the database edifice. Preliminary data collection procedures were discussed as well as the facility's role in handling these data. At this point, the role of the Informatics Core is minimal, however, further arrangements will be made as the study progresses.

Task 3, which does not apply to this annual report, involves conducting data analyses on all data collected and presenting/publishing findings.

a.	In collaboration with the Informatics Core	(Months 31-42)

Statistical Analyses of Data Obtained
b. Publicize Study Findings (Months 43-48)
c. Prepare Final Report for Granting Agency (Months 43-48)

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Held a meeting with members of the research team and an external advisory committee to discuss the development of the Phase II intervention.
- Conducted three Phase I focus groups with a total of 18 participants.
- Transcribed, coded and analyzed all focus group data.
- Continue to participate in regular project meetings with the Communications Core to discuss the redevelopment of the Phase II intervention.
- Preliminary data collection procedures have been established with the Informatics Core to initiate the database edifice with further plans to be developed as necessary.

REPORTABLE OUTCOMES

A total of 18 participants attended focus groups conducted between November 2002 and February 2003. The following is a summary of frequent responses from focus group participants:

- When asked to recall their thoughts and feeling at the time that treatment ended:
  - 8 participants expressed a feeling of exhaustion;
  - 5 participants felt relieved;
  - 5 participants were happy that their treatment was over;
  - 4 participants felt that it was just another step in the process and;
  - 3 participants reported feeling scared.
- When asked about issues about which that they would have liked more information before completing treatment:
  - 5 participants cited lymphedema;
  - 3 participants cited patterns of hair growth and;
  - 2 participants cited issues dealing with self-empowerment (i.e., healthy diet).
- When asked whether their feelings toward their body changed:
  - 3 participants said that they felt "different";
  - 3 participants felt that they lost their femininity and/or sexuality;

  - 3 participants felt that their illness changed their relationship with their husband/partner.
- When asked whether or not there was concern about cancer being a hereditary condition:
  - 4 participants stated that they worried about their family members;
  - 3 participants felt a sense of responsibility for having cancer and for passing this gene onto their family members.
- When asked whether or not treatment was effective:
  - 7 participants demonstrated a fatalistic attitude toward treatment effectiveness and cancer recurrence.

Below is a list of presentations and publications that are related to Project 3 activities.

- Presentations:

  Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., Babb, J. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Increasing Knowledge of Cancer Risk and Cancer Programs. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

- Publications:

  Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

  Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (in press). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention.

  Agrep, P., Campbell, F., Boccia, M., Goldman, B., Kass, N., McCullough, L., Merz, J., Miller, S.M., Mintz, J., Rapkin, B., Sorenson, J., Sugarman, J., and Wirshing D., (in press). Don't just talk louder/The medium is not the message. IRB: Ethics and Human Research, 25.

Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Miller, S.M., et al. (in press). Current research directions in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention.

Sherman, K.S., Miller, S.M., Sheinfeld-Gorin, S. (in press) Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington D.C.: American Psychological Association, in preparation.

Miller, S.M., McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Concerted efforts are being made to complete the development of the intervention in the next 1-2 months. Upon completion of this task, we will again begin conducting focus groups to assess and evaluate the effectiveness of the intervention design and delivery. Implementation of the Phase II intervention will begin after any final modifications to the intervention are made and approved by the FCCC IRB and the Department of Defense. As these processes are underway, we anticipate no further major obstacles and expect no major delays in the further progress of this project.

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DOD Progress Report, Project IV
Communication Skills Versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

Dr. Sharon Manne, Ph.D., Principal Investigator
Dr. Robert Schnoll, Ph.D., Co-Investigator

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer among American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, however, approximately 6% of breast cancer patients continue to develop metastatic disease. For the majority of women diagnosed with metastatic disease, median survival is approximately 18 to 24 months with systemic chemotherapy. The overall five-year survival rate for women with stage IV breast cancer is 21.3%. Thus, although a cure is not achieved for most patients, treatment improvements have made it possible for women to survive for relatively long periods of time with stable disease. Consequently, symptom relief and improvement in quality of life are critical therapeutic goals for this population.

The specific aims for Project 4 are as follows:

Aim 1: To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer.

Aim 2: To explore the effects of individual differences (e.g., ambivalence over emotional expression), treatment expectancies, social support and coping on the impact of the interventions.

This is a multi-site study, with prospective subjects being identified at the Fox Chase Cancer Center (FCCC), The Cooper Health System Division of Hemotalogy/Oncology and Temple University Hospital, and the Bryn Mawr Hospital (BMH) of the Main Line Health system. On-site physicians regularly provide the research assistant with a list of eligible patients who have given permission to be contacted for this study. Eligible participants are mailed a letter describing the study. Patients are approached and contacted in person by the Research Study Assistant during a clinic appointment, and the study is described in more detail. If the participant is interested in participating, informed consent will be obtained at that time. After obtaining written informed consent, the pre-intervention assessment packet is administered.

The study design is a randomized clinical trial, currently with three study conditions: 1) Communication and Support intervention, 2) Supportive counseling intervention and 3) Control (standard of care). Patients are assigned to one of these three conditions after the initial packet has been completed. The intervention programs are administered in an individual format with six in-person sessions and one telephone follow-up. Patients will be randomly assigned to therapists.

Consenting participants are stratified into groups having low or high baseline psychological distress and patients in each of the two strata are randomized to the intervention conditions.

The goal of this study is to determine whether an intervention targeted to women with breast cancer can impact their psychological distress. We have utilized a structured, CBT-oriented intervention that teaches effective communication and support skills because this type of intervention will assist patients in obtaining support from their existing support networks (rather than from other patients). Prior studies have suggested that deficits in support from partners and a lack of open engagement with partners are particularly problematic for female, late stage patients and among metastatic breast cancer patients. We have selected supportive psychotherapy as a comparison condition because this intervention will not provide skills, but will provide emotional support. In addition, this condition will provide a control for the non-specific effects of therapy (therapeutic bond, treatment expectancies, time and attention spent on the patient). We will examine the role of these non-specific factors in treatment outcome. We also will assess adherence to treatment protocol and treatment discrimination, which have been ignored in prior research. By focusing an individual difference variable (lack of support) that has been shown to predict a beneficial outcome for interventions, we may be more likely to elicit a response to treatment that has not been consistently found in prior studies of metastatic breast cancer patients.

BODY

Below are the specific tasks to be accomplished, as originally outlined in the Statement of Work, in the context of this Project 4. In addition, we have provided estimates of the amount of time it will take to complete these tasks.

Task 1 (Months 1-5): To refine the intervention manual for the support skills intervention and train psychotherapists in administration of both interventions.

a.	Recruit Focus Group Participants	(Months 1-2)
b.	Conduct Focus Groups	(Month 3)
c.	Analyze Focus Group Data	(Month 4)
d.	Train therapists in both conditions	(Month 5)
e.	Prepare study questionnaires, recruitment materials, materials for therapists	(Month 5)

Task 2 (Months 6-47).

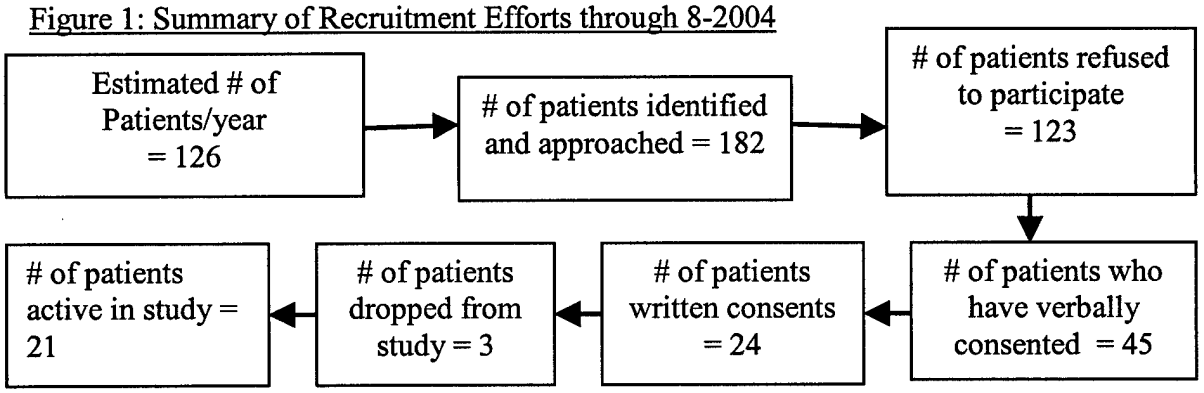
a.	Recruit participants	(Months 6-42)
b.	Administer study questionnaires	(Months 6-42)
c.	Conduct intervention sessions	(Months 4-43)
d.	Regular therapist supervision meetings	(Months 4-43)
e.	Enter study data	(Months 4-47)
f.	Conduct follow-up assessments	(Months 4-47)
g.	Treatment integrity checks	(Months 4-47)

Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop and tailor the intervention material. The training of project therapists (1d) was completed as scheduled. Though questionnaires and therapist materials were completed as scheduled (1e), there was some delay and in the production of recruitment materials due to nature of the multi-site IRB approval process. Materials have included posters, letters (signature stamped by prospective participant's oncologists), pamphlets, and stickers to be attached to eligible patients medical charts. Currently all recruitment materials have been approved.

Though recruitment (2a) has begun, there was approximately a 4-month delay in start-up due to multiple protocol amendments, and their respective DoD and multi-site IRB approval requirements. Study questionnaires and conducting of intervention sessions (2b, 2c) commenced after the start-up delays, and has kept pace with recruitment. Frequent therapist supervision (2d) has not been necessary thus far, as the slow recruitment has allowed the interventionists to give and receive feedback, with the PI and Project Manager, after each intervention session has been conducted. The PI and Project Manager have met several times, at irregular intervals, with the interventionists throughout the year. It is anticipated that, as recruitment rises, more formal, regularly scheduled supervision will be held with the interventionists. Data entry (2e) has been done concurrently with recruitment and intervention sessions. Project 4 staff has worked closely with the Informatics Core in order to develop data entry protocols, computerized data entry form screens, and a system which allows Project 4 staff to be automatically notified when different questionnaire elements are due to be sent to patients. Thus far, it has been unnecessary to conduct any follow-up assessments or treatment integrity checks (2f, 2g), as no individual has completed the six-session intervention. We anticipate that the enrolled individuals receiving an intervention will be completing it in a few weeks. Intervention sessions are audio taped for treatment integrity-tracking purposes.

Sluggish recruitment continues to be a significant issue in the second active year of the Project 4. Bryn Mawr Hospital has been added as a study site, but identification and recruitment figures continue to be lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Below, in Figure 1, we summarize our recruitment efforts to date.

Figure 1: Summary of Recruitment Efforts through 8-2004



We have attempted to address both issues through a variety of methods. In addition to adding Bryn Mawr Hospital as a study site, a protocol amendment to remove the "within 4 months of diagnosis" eligibility criterion was approved. Additionally, a protocol amendment, that allows women diagnosed with stage 3b breast cancer, to be eligible has been approved by the Fox Chase Research Review Committee.

Several changes to the protocol have been undertaken in order to reduce the refusal rate of approached eligible patients. Changes approved by the DoD and currently undergoing FCCC IRB review include financial reimbursement, of up to $225.00, to participants and the removal of some study assessment instruments to reduce the length of time necessary to complete each assessment. The length of surveys has been identified as a factor in a patient's decision whether or not to participate.

Finally, in order to increase the power of the data collected from individuals actually enrolled in Project 4, the Control arm of the study will be removed, pending FCCC IRB approval. Thus, all enrolled patients will receive one of the two study interventions. We believe that these protocol changes will effectively boost study enrollment to the originally anticipated number.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Actively recruiting patients, both at FCCC and satellite sites.
- Actively administering the experimental interventions.
- Further development and tailoring of the interventions.
- Trained the interventionist.
- Further development of the recruitment procedures.
- Finalization of study assessment instruments.
- Utilized Informatics Core to develop and maintain data collection and management procedures.

REPORTABLE OUTCOMES

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point.

- Presentation

Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

CONCLUSION

Task 1-study elements have been completed. Task 2 elements, including recruitment, intervention and data collection are well underway. We estimate that preliminary data analysis will begin sometime in the next reporting year (10/2003-10/2004). Thus, no analytical conclusions can be drawn at this time.

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None

DOD Progress Report
Leadership Core

Dr. Suzanne M. Miller, Ph.D.
Principal Investigator
Core Director

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Under the direction of the Leadership Core, the development of the Behavioral Center of Excellence in Breast Cancer (BCE) has been guided by a unifying cognitive-affective processing (CAP) approach to breast cancer prevention and control that has informed the specific hypotheses of each project and has dictated the relevant interventions and assessments, and that provides a multidisciplinary linkage across projects. The senior leadership and administrative support core component is designed to ensure scientific collaboration, guidance, and integration across the research projects and to promote the efficient administration of all the components of the BCE grant. Through collaboration between the principal staff on the main projects and other cores, the Leadership Core is able to broaden past and ongoing research by pursuing a closely coordinated research program to modify attitudes, behavior patterns, and lifestyles in ways that will ultimately reduce breast cancer incidence, morbidity and mortality effectively, thus directly addressing the mission for consequential behavioral research in breast cancer.

The specific aims of the Leadership Core are as follows:

Aim 1: To provide oversight, and management of, all aspects of the BCE to maximize the efficiency of its integrative, inter-coordinated organizational structure.

The Leadership Core for the BCE is intended to be a resource to the Center as a whole, as well as to function as the administrative resource for each of the individual projects.

Aim 2: To continue to develop, refine, and evaluate the overarching, unifying conceptual framework.

In order to continually refine the guiding theory of research within the BCE, the Leadership Core will integrate data across projects to more comprehensively address the dynamics of the interactions between construals and the other cognitions and affects that they prime and activate within the processing system, as the individual interprets, transforms, and acts on diverse types of cancer risk information (Miller & Diefenbach, 1998).

Aim 3: To oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically derived assessments and interventions.

The Leadership Core will function to ensure that the project investigators create and tailor the CAP interventions to target the entire pattern of intervening cognitive and affective dynamics that underlie effective modulation of distress and long-term adherence to breast cancer prevention-control behaviors.

Aim 4: To develop actuarial predictive indices of cognitive-affective processing types.

With oversight from the Leadership Core, a goal of the BCE is to clarify and harness Person x Situation interactions emphasized by the C-SHIP model. This requires a shift from global to specific, contextualized analysis and assessments.

Aim 5: To oversee and guide the planning, development, and implementation of new BCE projects.

By building on the strong network of projects already proposed, the vision of the BCE is to develop further studies that are relevant to the CAP agenda and that interact synergistically with the ongoing work.

Aim 6: To administer the Training Program.

The Leadership Core will oversee the implementation of the pre- and post- doctoral training program through the identification of qualified candidates with ambitions to pursue careers in behavioral medicine and the development of communications to enhance cancer prevention and control.

BODY

According to our Statement of Work the plan during Year 1 was to accomplish the following tasks: 1) to convene Advisory Committee and scientific meetings; 2) to oversee implementation of core functions and to oversee initiation of projects and cores; 3) to implement the Training Program and, 4) to develop, refine, and evaluate the overarching, unifying conceptual framework.

Task 1. To convene advisory committee and scientific meetings.

The External Advisory Committee, which was chosen to provide consultation for the BCE senior staff, held its first meeting in December 2002 at FCCC. The committee reviewed the original plans of each research team as well as the program progress and provided advice and consultation on the outcome, interpretation, and direction of the research program. Members of the Advisory Committee present at the meeting were Chanita Hughes, Ph.D., Assistant Professor, Department of Psychiatry, University of Pennsylvania and Howard Leventhal, Ph.D., Center for Research on Health and Behavior, Rutgers University. At this meeting, each project and core leader presented a brief summary of the current status of their project/core as well as accomplishments made over the year. External committee members addressed any specific questions and concerns of the Investigators and provided recommendations for successful implementation and maintenance of the projects and cores. Issues that were addressed included improving recruitment rates, particularly among African American patients (Project 1); choosing variables for tailoring and the mechanisms by which tailoring of health information is thought to enhance behavior change (Project 2); the most appropriate mode, intensity/frequency, and timing of intervention delivery and the most important focus of the intervention for enhancing preparation and skills for dealing with

cancer survivorship (Project 3); standard strategies to increase study acceptance rates and possible collaborative sites in the Delaware Valley (Project 4). In response to these concerns the external advisors offered many recommendations including the use of community centers to access African American populations, the benefits of addressing the informational needs of patients with varying levels of health-risk information processing styles, providing cancer survivors with information to realistically anticipate the lingering effects of adjuvant treatment as well as a follow-up session to reinforce symptomology expectations, directing patients to support groups and counseling sessions as necessary, and using qualitative data as a way of identifying individual concerns. This meeting lasted approximately 3 hours. The Committee will hold its next meeting in the next 3-6 months.

Second, Dr. Miller, Director of the BCE, spearheaded the organization of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO). The second annual Behavioral Oncology Interest Group sponsored a Study Group Breakfast in March 2003. Dr. Miller and other members of the BCE Leadership Core joined forces with the Institute of Medicine National Cancer Policy Board to hold a joint breakfast for the Behavioral Oncology and Tobacco Interest Groups. Prior to the annual ASPO conference, IOM's National Cancer Policy Board released a report entitled, "Fulfilling the Potential for Cancer Prevention and Early Detection" which included a detailed analysis of the potential reductions in morbidity and morality from modification of behavioral risk factors related to tobacco, diet, and physical activity as well as participation in recommended screening for early detection; a complete review of the treatment outcome literature for these target behaviors, an assessment of current practice in health care related to delivery of proven interventions, and an assessment of funding initiatives. The report also made a series of policy recommendations for federal and private sector initiatives to increase the rates of adoption, the reach, and the impacts of evidence-based cancer prevention and early detection. The focus of the breakfast session was a highlight of the 12 recommendations made in this report, followed by a panel discussion of the recommendations and an executive summary. The results from these meetings will be recorded and submitted. In addition, last year's results, which focus on the standard for state-of-the-science behavioral research in behavioral oncology, will be published in *Cancer Epidemiology, Biomarkers, and Prevention.*

Third, the Leadership Core has established the Behavioral Medicine Speakers Series at Fox Chase Cancer Center. The following speakers were invited to present their most current data to the Division of Population Sciences:

- Natalie Hamrick, Ph.D., Fox Chase Cancer Center, spoke on "Quality of Life and Cancer Survival and the Use of Religion to Cope with Cancer" on July 29, 2003.
- Guy Montgomery, Ph.D., Ruttenberg Cancer Center, Mt. Sinai, spoke on "An Integrative Approach to Behavioral Medicine" on July 22, 2003 (Hosted by Sharon Manne).
- Marla Gold, MD, Drexel School of Public Health, spoke on "Public Health in the 21st Century" on June 10, 2003.

- Mary B. Daly, MD, Ph.D., Fox Chase Cancer Center, spoke on "Communicating Genetic Test Results to the Family" on April 1, 2003.
- Amy Lazev, Ph.D., M.D. Anderson Cancer Center, spoke on "Smoking Cessation: Reaching Those Most in Need" on February 11, 2003.
- Robert Schnoll, Ph.D., Fox Chase Cancer Center, spoke on "Tobacco Control Research at FCCC" on January 7, 2003.

Task 2. To oversee implementation of core functions and to oversee initiation of projects and cores.

The Leadership Core continues to hold monthly BCE meetings. Principal Investigators, Co-Investigators, Project Managers of the various BCE projects and Core staff attend these meetings that provide an opportunity for investigators to exchange ideas and provide input across studies. Agenda items include: 1) Updates from each project and core; 2) Training Program status; 3) DoD reporting requirements and IRB documentation; 4) Standardization of assessment tools across studies to maximize opportunities for meta-analysis; and 5) Cooperative strategies to enhance recruitment across studies. Meetings minutes are kept to record the current status of each study. Specifically:

- Discussions have been organized to enhance cooperative efforts to identify eligible participants across studies drawing from the same recruitment source. BCE members have provided assistance in modifying the focus groups and changing the recruitment strategy for Project 1 in order to facilitate the acquisition of sufficient participation. Further, recruitment strategies have been considered to accommodate potential overlap in the recruitment process for Projects 2 and 3. It has been established that the Informatics Core will flag prospective participants who meet eligibility critieria for both Projects 2 and 3. The Leadership Core has also instituted an introductory presentation for the patients of the Breast Evaluation Clinic that provides an overview of the BCE to potential participants during their initial visit.

- Focus has been placed on the theoretical applications of the C-SHIP model in the development of tailored communications. Progress has been made on refining the theory in an effort to assist projects in the development of effective communications. For example, vital input from staff from different projects and the Leadership Core have helped to refine the intervention protocol and assessment tools for Project 2. Additionally, members of the BCE assisted in the completion of the content for the tailored message library and corresponding print materials using input from external advisors combined with their own expertise. Suggestions for recruitment strategies have also been made at BCE meetings resulting in the initiation of additional recruitment at FCCC. BCE members also participated in ongoing discussions regarding the most effective and productive methods for working with Network and affiliated sites to gain regulatory approval and subsequent recruitment of subjects at each site.

- Monthly BCE meetings have been instrumental in providing feedback to considerations presented for the development of the intervention protocol for Project 3. Members of the Communications Core, as well as leaders of other BCE projects, have provided valuable advice at the meetings for the coding and analyzing of data collected through Project 3 focus groups and suggestions for using these data to further refine the intervention.

- Project 1 focus group data were presented at a recent BCE meeting. Members of the research study presented the results of the qualitative analysis from Phase 1 of this project (i.e., focus groups with first-degree relatives of African American breast cancer patients) to the entire BCE project staff. The goal of this presentation was to share with the entire BCE staff the results and to solicit feedback concerning the quality of the analysis and the need for additional assessment. Following a PowerPoint slide presentation of the focus group results, BCE personnel offered feedback and interpretation of the study results. For instance, the need to reanalyze certain focus group questions to refine specific themes was mentioned and these analyses were subsequently performed. Overall, the entire BCE staff provided critical feedback for the development of the assessment tool that was yielded from these qualitative analyses.

Task 3. To implement the Training Program.

The following has been implemented to support the BCE Training Program:

Three FCCC faculty members serve on a BCE Fellowship Search Committee who were selected by members of the Leadership Core. This committee holds the responsibility of disseminating an announcement about pre- and post-doctoral fellowship opportunities, developing an evaluation procedure, arranging for candidate interviews, and selecting candidates. The committee is comprised of Dr. Robert Schnoll, Dr. Mary Daly, and Dr. Eric Ross, who meet over the course of the year to devise fellowship announcements and candidate review criteria. The following review criteria are used to evaluate potential candidates: Ability in Written Communication, Familiarity with Behavioral Oncology in General, Familiarity with Breast Cancer in Particular (Behavioral and Medical issues), General Research Experience, Apparent General Research Proficiency, Commitment to Research Career in Behavioral Oncology/Cancer Prevention and Control, Quality and Relevance of Academic Training, Enthusiasm for Fellowship, Convergence Between BCE Projects and Applicant's Experience, Convergence Between BCE Projects and Applicant's Career Goals.

Pagona Roussi, Ph.D., has recently joined the Psychosocial and Behavioral Medicine Program. Dr. Roussi will be serving as a consultant to Dr. Miller and members of the research team on several ongoing grants. Dr. Roussi comes from Aristotle University of Thessaloniki, Thessaloniki, Greece offering expertise in stress and coping with major life events, with a special interest in serious illnesses. Dr. Roussi has a Ph.D. in Chemistry earned at Imperial College, London University, London, England in 1977. Since earning her Ph.D. in Clinical Psychology at Temple University, Philadelphia, Pennsylvania in

1995 Dr. Roussi has taught in the Department of Philosophy and Social Studies at the University of Crete, Crete, Greece as a Visiting Assistant Professor as well as in the Department of Psychology at Aristotle University of Thessaloniki, Thessaloniki, Greece. She has several publications, both independently and in collaboration with Dr. Miller and other Investigators. Her responsibilities at FCCC include analyzing data, writing manuscripts, and providing consultation and assistance with the designing of new interventions. Specifically, she will be involved in the development of the intervention protocol for Project 3.

Amy Lazev, Ph.D. joined FCCC in July 2003 as an Assistant Member in the Psychosocial and Behavioral Medicine Program. Dr. Lazev comes to FCCC from the Department of Behavioral Science at the University of Texas M.D. Anderson Cancer Center. She received her Ph.D. in Clinical Psychology in 2002 from the State University of New York at Binghamton. Dr. Lazev has collaborated with Investigators at M.D. Anderson and the H. Lee Moffitt Cancer Center in developing innovative smoking cessation interventions for at-risk and patient populations. She is currently developing a research study investigating the prevalence of smoking in breast cancer patients. This project will examine smoking prevalence among women at all stages of treatment and psychosocial barriers to quitting smoking prior to surgery. Results of this study will be used to design a smoking cessation intervention targeted and tailored to the unique needs of breast cancer patients. Dr. Lazev's expertise in the area of smoking cessation, special populations, and patient studies, will make significant contributions to tobacco control and breast cancer research at FCCC.

Catia Ghinelli, Ph.D., also joined FCCC as a visiting researcher from Policlinico di Modena, Modena, Italy in August 2003. She came to the Psychosocial and Behavioral Medicine Program to learn about research currently being conducted under Dr. Miller using the Miller Behavioral Style Scale (MBSS), a scale developed by Dr. Miller to determine an individual's attentional style in response to a health threat, which will lay the groundwork for future collaborations between Fox Chase and Policlinico di Modena using MBSS. Dr. Ghinelli will also work on extending Project 3 into an Italian sample of breast cancer survivors.

In addition, Elizabeth Cahill Bernabeo, MPH, Ph.D. candidate in the Graduate School of Social Work and Social Research at Bryn Mawr College, joined FCCC as a collaborator in May 2003 to conduct research that will support the dissertation phase of her Ph.D. in Social Work. Ms. Bernabeo has extensive research experience in projects aimed to improve the access to and quality of care. Her main research interests lie in Behavioral Medicine, particularly, understanding how individuals adapt to disease labels, whether or not these labels, in addition to other psychosocial factors affect health behavior, the role of psychosocial and/or environmental factors in an individual's ability to cope with disease, and how all of these factors relate to present and future health policy. Her focus at FCCC will be on developing qualitative approaches to assess women's responses to BRCA 1/2 testing and their understanding of the results.

Jenna Johns, MPH candidate at Temple University, Philadelphia, PA, will be collaborating with members of the BCE to complete her Thesis Project. Ms. Johns has a strong background in the area of nutrition, disease promotion and prevention. She will contribute to ongoing research at FCCC on a part-time basis through May 2004, using cognitive science techniques to carefully examine how women at-risk for breast cancer process their risk information.

Finally, Kerry Sherman, Ph.D., who began in 2002 in post-doctoral positions returned to University of Macquarie, Sydney, Australia in June 2003. Dr. Sherman came to FCCC with a special interest in developing behavioral protocols to enhance adaptation to breast cancer survivorship and to reduce psychological and medical sequalae associated with breast cancer treatment (e.g., lymphedema). During her stay at FCCC, she implemented a research study to understand the cognitive-affective factors predicting adherence to, and uptake of, lymphedema risk minimization practices. She was also contributed to BCE Project 1 through additional collection of data and providing assistance in data analysis.

The Summer Internship Program continued to operate through Summer 2003. The Summer Internship program was established in 2002 to provide training opportunities to students at the high school, undergraduate and graduate levels in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field and to provide a source of candidates for the Training Program. Two interns joined us in the summer of 2003: Jaime Walker, a senior at Penn State University, PA and Jamie Rodriguez, joining us to fulfill the requirements for her Bachelors degree in Psychology from East Stroudsburg University, PA. Each intern was required to complete a web-based bioethics course, was provided with required readings highlighting the theoretical framework that guides our research, and was responsible for conducting study-related literature searches using electronic databases such as PubMed and Ovid as well as retrieving journal articles electronically and from FCCC's on-campus library. In addition, Jaime Walker was involved in transcribing qualitative focus group data which described women's thoughts and concerns as they completed adjuvant therapy for primary breast cancer, organizing and cataloging over 7,000 articles for the BRCF resource library, and participating in team meetings.

Task 4. To develop, refine, and evaluate the overarching, unifying conceptual framework.

Guided by the C-SHIP framework, members of the Leadership Core have applied to the theory a comprehensive analysis to breast cancer risk. This work was spotlighted at the Era of Hope Breast Cancer Research Conference in Orlando, Florida in September, 2002. Dr. Suzanne Miller was an Invited Keynote Plenary Speaker on: Cutting edges of behavioral research in the prevention of breast cancer. In this talk, Dr. Miller highlighted the state-of-the-science with respect to breast cancer prevention and control with emphasis on the theoretical underpinnings and empirical approach to the design, development, implementation, and assessment of tailored health communications across the breast cancer spectrum. The leadership framework is also being developed and

extended to the other cancer models, including prostate, ovarian, lung, head and neck, colorectal, and cervical.

The Leadership Core has contributed an extensive list of articles based on its literature search on breast cancer risk to the library of the Behavioral Research Core Facility (BRCF) at Fox Chase Cancer Center under the direction of Dr. Suzanne Miller. The BRCF provides the necessary infrastructure and resources to integrate basic and applied biobehavioral and psychosocial research across the spectrum of cancer prevention and control research. Its mission and function are synergistic with that of the BCE. The BRCF library serves as an NCI- funded resource to investigators throughout the institution.

KEY RESEARCH ACCOMPLISHMENTS

- Held the first of a series of External Advisory Committee meetings.
- The continuation of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
    - The continuing support of the BCE Training Program Committee that oversees the development and implementation of promotional strategies to enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.
    - Pagona Roussi, Ph.D., has joined the Behavioral Medicine Program as a consultant on the various projects within the BCE.
    - Interviews continue to be conducted to fill the remaining post-doctoral position within the Training Program.
    - The Summer Internship Program continued successfully for its second year in providing training opportunities to students at the high school, undergraduate and graduate level in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field.
- The continuation of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).
- Preparation of two volumes that will extend the theoretical model across the cancer continuum, including genetic risk, and provide an integrative synthesis of the behavioral medicine field.

REPORTABLE OUTCOMES

At this time, the Leadership Core continues to provide integrative oversight and management of all aspects of the BCE to maximize the efficiency of its inter-coordinated organizational structure. The Core continues to develop, refine, and evaluate the overarching, unifying conceptual framework in its efforts to oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically-derived assessments and interventions. The Core remains active in the ongoing maintenance of the Training Program.

- Presentations:

  Fleisher, L., Miller, S., Schnoll, R., Mckeown, N., Brower, ., L., Rodoletz, M. 27th Annual Meeting of the American Society of Behavioral Oncology. Poster presented on: Improving High Risk Women's Preparation for Genetic Counseling: A Pilot Study in the Atlantic Region CIS, March, 2003.

  Miller, S.M. Fox Chase Cancer Center. Conference on: Light, Circadian Disruption, and Breast Cancer. Speaker on: Puberty, depression and behavior: Alcohol, tobacco and breast cancer risk. Phila., PA. March, 2003.

  Miller, S.M. Invited Colloquium, University of Bologna (Faculty of Psychology), Foundations and Applications of Health Psychology: The Example of Cancer. Bologna, Italy. May, 2003.

  Miller, S.M. Invited Colloquium, University of Bologna (Faculty of Psychology), Theory and Research in Cancer: Applications of Genetic Risk. Bologna, Italy. May, 2003.

  Miller, S.M. Invited Colloquium, University of Bologna (Faculty of Psychology), Theory and Research in Cancer: Applications to Screening, Disease, and Smoking Cessation. Bologna, Italy. May, 2003.

- Publications:

  Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

  Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (in press). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention.

  Agrep, P., Campbell, F., Boccia, M., Goldman, B., Kass, N., McCullough, L., Merz, J., Miller, S.M., Mintz, J., Rapkin, B., Sorenson, J., Sugarman, J., and

Wirshing D., (in press). Don't just talk louder/The medium is not the message. IRB: Ethics and Human Research, 25.

Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Miller, S.M., et al. (in press). Current research directions in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention.

Sherman, K.S., Miller, S.M., Sheinfeld-Gorin, S. (in press) Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington D.C.: American Psychological Association, in preparation.

Miller, S.M., McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Members of the BCE continue to successfully assist all research teams accomplish their tasks during its second year. Our efforts have remained focused on the development of the necessary infrastructure between project staff and the other core facilities in order to facilitate synergistic research efforts and integrative findings across the multiple projects.

REFERENCES

None

DOD Progress Report
Informatics Core

Suzanne M. Miller, Ph.D., Principal Investigator
Eric Ross, Ph.D., Core Director

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The varied populations studied in this Behavioral Center of Excellence in Breast Cancer (BCE) and the complexity of the designs require development of study-specific computer based tools to provide critical project management and coordination, and for the collection, validation, storage, retrieval and analysis of data. The projects contained in this BCE include: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved, Cancer-A Teachable Moment Within the Family: From Concept to Community, Facilitating Re-entry Following Treatment for Primary Breast Cancer, and Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer.

The objective of this core is to facilitate the research conducted in this BCE by providing (1) a central repository for all of the data included in the research, (2) data entry and validation services and (3) report generation and standard statistical program services. To be included in this core data repository are: a) socio-demographic data on study populations, b) clinical information, c) family history, d) genetic testing data, e) psycho-social data, f) health history data, g) quality of life data, h) cancer screening data, and i) diet data. Data from approximately 1000 subjects collected in four research projects will ultimately be stored in this information system.

The specific aims of the core are:

Aim 1: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

Aim 2: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems.

Aim 3: To provide high-quality data entry services.

Aim 4: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality.

Aim 5: To provide statistical computing support.

BODY

Below, we specify the tasks to be accomplished in the context of this project.

Task 1. Provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research. (Months 1-47)

a. In collaboration with the project investigators and research teams clearly

define the specifications of the required information systems
b. Carefully design the needed database structures
c. Develop database systems
d. Design, and develop electronic data entry/retrieval systems
e. Test the electronic data entry/retrieval systems
f. Design and develop report and letter generation software
g. Test report and letter generation software
h. Review of applications by Project Investigators
i. Make modifications as needed. Put software into production
j. Support and enhance software system software as needed

Task 2. Ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems. Provide data entry and data validation services. Provide statistical computing support. (Months 3-48)

a. In collaboration with the project investigators and research teams design, develop and test data quality assurance systems
b. Conduct data entry and data validation
c. Provide statistical programming services

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.

- Core staff collaborated with project investigators and research staff to refine the data flow and hardcopy data collection instruments for Projects II and IV. Core staff developed data dictionaries based on study requirements and data collection instruments.

- Core personnel have designed and developed comprehensive information management systems to meet the specific needs of projects II and IV. These customized relational database systems have been implemented using ORACLE database software. The database and management structure facilitate efficient data capture and manipulation, as well as control the exchange of information across the projects. All software has undergone thorough testing before release to the user community.

- Client-server and web-enabled electronic data entry/retrieval and report generation software have been developed for Projects II and IV using Oracle's Developer/2000 suite of products.

- Data quality assurance procedures have been implemented for Projects II and IV, using software-based data entry checks as well as post-entry manual audits.

- Software for the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires has been developed for Project II.

- Software was developed, for Projects II and IV, to generate reports that allow tracking of study accrual and progress of individual study subjects.

- All FCCC computers used for storing the information were protected from inappropriate outside access by the FCCC firewall.

- New security measures for accessing data (vis-à-vis HIPAA regulations) have been implemented. The first level controls access to the desktop computers and web-server. Fox Chase Cancer Center uses a Lightweight Directory Access protocol (LDAP) directory service, implementing a subset of the InteOrgperson/EduPerson V2.0 schema, to provide a robust, extensible, and well-controlled common authentication mechanism. The second level of username/password based security takes place at the database server and application interface level. Each user is assigned a unique Oracle username/password. Restrictions are applied to each user commensurate with their needs to access the data (roles) at the application level.

REPORTABLE OUTCOMES

The details of the information system developed for the three research projects are described below.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved

The overall goal of Project I is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and adherence to breast cancer screening recommendations among African American women. Project I has completed conducting focus groups to discuss issues related to breast cancer awareness and screening. Design, development, testing and deployment of the production database for phases 2 and 3 of the project will begin following IRB approval.

Project II: Cancer – A Teachable Moment within the Family: From Concept to Community

The goal of this study is to test the effectiveness of a tailored intervention to increase participation rates in a FCCC high-risk breast cancer program (i.e., FRAP). A secondary aim is to explore the effect of the intervention on breast cancer screening practices.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. The relational database management system for this project is nearly complete (the database/interface for the 12

month follow-up questionnaire awaits IRB approval of the instrument). This system will maintain all of the information collected in this study including: health history, clinical, epidemiologic, socio-demographic, and psychosocial data. In addition, this database contains cancer and vital status data on relatives of individuals recruited into the study. The software system coordinates numerous tasks, including the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires. This system generates multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data can be updated from follow-up information to include deaths or new cancers reported for study subjects, previously listed family members, as well as new births. The system randomizes participants to study arm based on strata defined by the participant's MBSS score, her family history (of cancer) and date of last mammogram. Tailored and control scripts are automatically generated at time of randomization using Oracle Reports. All software has undergone thorough testing.

Project III: Facilitating Re-entry Following Treatment for Primary Breast Cancer

The primary objective of this study is to develop and evaluate a C-SHIP guided Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry, following adjuvant treatment for primary breast cancer. Core staff reviewed draft data collection instruments and project timelines. Project III has completed its first set of focus groups to help refine the cognitive-affective intervention. Design, development, testing and deployment of the production database for the randomized trial will begin following the completion of the second set of focus groups and finalization of the data collection instruments and study timelines.

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

The goal of this study is to compare a cognitive-behavioral intervention (with a communication and support training focus) to a supportive therapy intervention, on the quality of life of women with metastatic breast cancer. A secondary aim is to explore moderating effects of individual dispositional factors and mediating effects of support-related variables on the impact of the intervention strategies.

The relational database management system for this project has been completed. This system maintains all of the information collected in this study and facilitates many aspects of data collection and patient tracking. Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. Data dictionaries were prepared by Core staff. A case tool (PowerDesigner 6.1.0) was used to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, and generate a report as an html file.

A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was developed. All software has undergone thorough testing by demonstrating that each function is operational and performs according to specification. Views of the database have been created to facilitate analysis by investigators and study biostatisticians using SAS and SPSS.

- Presentations

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

CONCLUSION

This Core will serve as a resource for the Center of Excellence as a whole and will maintain a valuable source of data for current and future studies. By centralizing these services into an Informatics Core, we will be better able to manage and coordinate the collection, storage, and distribution of a large amount of highly valuable data. Subject to informed consent, the information contained in the data repository will be available to all investigators in the Center of Excellence. By providing access to the data to all participants, sharing technical capabilities and ensuring the quality of the data, this core will not only facilitated achievement of the aims of the individual projects, but also make possible exploratory analyses beyond the stated aims of the projects.

REFERENCES

None

DOD Progress Report
Communications Core

Suzanne M. Miller, Ph.D., Principal Investigator
Michael A. Diefenbach, Ph.D., Core Director
Linda Fleisher, MPH, Co-Core Director

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The Communications Core has provided critical support and services for the research projects in the Behavioral Center of Excellence in Breast Cancer (BCE). The Communications Core builds on and extends the infrastructure, resources and expertise of the FCCC Behavioral Core to include state-of-the art communications theory and applications.

The Communications Core has two primary functions. The first, descriptive function consists of assessing information needs and culturally specific beliefs of populations targeted by the different Center projects. The second primary function of the Communications Core is to successfully translate this information into effective communication messages and strategies that meet the needs of the target population. To this end, the Communications Core conducts in-depth needs assessments of the target populations through focus groups for each individual research project; analyze the information obtained; and assist in developing appropriate patient-tailored health communications.

Specifically, the aims of the Communications Core are:

Aim 1: To provide linkages to the FCCC Behavioral Core for assistance in evidence-based behavioral approaches and measures.

Aim 2: To expand the Behavioral Core resources to include communication theory and applications.

Aim 3: To facilitate the assessment of information needs of the target populations through focus groups.

Aim 4: To provide consultation in the development of interventions using behavioral, health education and communication principles and theories.

Aim 5: To provide formative evaluation services (e.g. implementation and analysis) to inform the development and pilot testing of interventions for specific populations.

By utilizing the Communications Core for all research projects an economy of scale is created with a synergistic impact that benefits and informs each of the projects as well as the entire Behavioral Center of Excellence.

These goals are achieved through a structured consultation and implementation process that includes an initial contact and needs assessment phase, a planning phase, and an implementation and follow-up phase. Throughout these phases, members of the Communications Core and members of the individual research projects have been in frequent contact to ensure that the objectives of the individual research projects are achieved.

BODY

In year 2 the Communications Core initiated the various tasks for each research project as specified in the Statement of Work and as listed below. The specific tasks by research projects were. The specific tasks by research projects are:

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved.

The major task for Project 1 was to assist in the refinement of the psychosocial familial risk questionnaire for low-income African American women. Specifically:

Developed analysis plan for focus group	Month 1
Assisted in recruiting focus group participants for Phase 1	Months 2-3
Assisted in conducting the focus groups	Months 4-5
Assisted in the analysis of focus group data	Months 6-7
Assisted in developing the assessment instrument	Months 7-12

Project II: Cancer-A teachable Moment Within the Family: From Concept to Community

Created tailored, personalized messages for experimental Intervention	Months 1-6
Assisted in creating scripts for control group	Months 4-6
Created tailored fact sheets to accompany tailored messages	Months 6-8
Created fact sheets for control group	Months 6-8
In collaboration with Informatics Core assisted in drafting follow-up letter	Months 9

Project III: Facilitating Re-entry following Treatment for Primary Breast Cancer

Conducted three focus groups (N=18) to explore and assess the concerns expected by the study population for their transition into the post-treatment, re-entry phase of breast cancer.	Months 3-4
Assist in compiling a report based on the focus group transcriptions	Months 5-6

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

Assist investigators in developing refined recruitment protocols and materials.	Month 5

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.

- Members of the Communications Core have augmented the library of the Behavioral Research Facility with articles from the communications literature. This resource is made available to all members of the BCE, as well as the wider community of researchers at FCCC. Further, project-specific accomplishments follow:

- **Project I.** In collaboration with project staff the Communications Core has assisted in the recruitment and conduct of the focus groups as well as their analyses. The Core has provided background materials on designing focus groups and evaluating focus groups data. One of the Core Members, who is a trained focus group facilitator, conducted the groups in collaboration with Dr. Andrea Barsevick, Co-Investigator.

- **Project II.** The Core met a number of times with the research team and the Biostatistics team to refine the communications and technical specifications for the tailored intervention. Collaboratively, members of the Communications Core and the research team then developed the algorithm and messages for tailoring to information-seeking tendency (low or high monitors). We have developed messages that contain pertinent information about family history of breast cancer and screening recommendations. Each one of these messages has been adapted to the needs of high and low monitors. Message development has been a multi-step process involving the writing of several drafts that are checked for factual accuracy and ease of use by the research team, and beta-testing of versions of the tailored telephone counseling protocol with project staff to ensure flow and organization. In addition, we have developed tailored fact sheets that accompany the tailored messages.

- **Project III.** Members of the Communications Core have regularly met with members of the research team to develop the focus group guide, discuss recruitment methods and go over logistical aspects of conducting the focus groups. The focus groups were conducted by members of the Communications Core and have been transcribed and evaluated.

- **Project IV.** The research team and members of the Communications Core have developed refined recruitment strategies.

REPORTABLE OUTCOMES

Other than the key research accomplishments detailed above there are no reportable outcomes.

- Presentations

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during their second year. Our efforts have focused on refining the tailoring process and message library, developing tailored fact sheets, preparing for focus groups including the development of focus group guides, and developing analysis plans for focus group data. Further we have discussed and developed recruitment strategies and refined recruitment and intervention materials. We have also continued to add to the BRCF library by identifying and including key health communication research articles.

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None

DOD Progress Report
Blood Collection and BRCA1 and BRCA2 Mutation Testing through the Genetic Susceptibility-Testing Laboratory Core

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Andrew K. Godwin, Ph.D., Core Director

10/16/03

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The strongest known epidemiological risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with their increased risk of developing cancer. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. This Core was created to support Project 2, "Cancer-A Teachable Moment Within the Family; From Concept to Community" and Project 3, "Facilitating Re-entry following Treatment for Primary Breast Cancer". Project 2 proposes to test the efficacy of a health communication message personalized to a set of demographic, clinical, and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attributed to the recent diagnosis in a first-degree relative (FDR). The purpose of the health communication message is to encourage that these at-risk women participate in the Family Risk Assessment Program at FCCC or the Network Hospitals in order to receive personalized breast cancer risk information provided to the participants. *BRCA1* and *BRCA2* mutation analysis is offered to those who have familial patterns of breast cancer indicative of a possible involvement of a disease-associated germline mutation. Similarly, Project 3 proposes to provide tailored communications. However, the communications are provided to breast cancer patients actively undergoing treatment. The communications are designed to enhance adjustment, quality of life, and adherence to recommended follow-up regimens during survivorship. Participants are extended an offer to participate in FRAP to receive familial risk information. Eligible participants, based again on family history of breast cancer, are offered *BRCA1* and *BRCA2* mutation analysis.

Specifically, the aims of the Core are as follows:

Aim 1: To collect and bank blood samples from women with breast cancer or unaffected women with a family history of breast cancer as part of Projects 2 and 3.

Aim 2: To evaluate constitutive DNA from individuals participating in the Projects 2 and 3 for mutations in BRCA1 and BRCA2.

We have an extensive history of collecting and banking biospecimens from women at an increased risk for breast and/or ovarian cancer at the Fox Chase Cancer Center. During the past year we collected and processed blood samples from hundreds of FRAP participants and have screened for germline mutations in *BRCA1* and *BRCA2*. We have improved our methods to identify germline mutations as well as to assess the impact of these mutations on cancer risk. To date, we have identified more than 400 *BRCA1* and/or *BRCA2* mutation carriers (including 48 unique deleterious mutations) using our EMD

approach. The personnel and methodology are in place to handle and screen the BCE samples as they are obtained. We attend the monthly BCE meetings to discuss recruitment and to up date the progress we have made in our genetic testing.

BODY

The strongest known epidemiologic risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with increased risk. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. We developed this Core base on our previous experiences in effectively collecting thousands of blood samples from research participants with family histories of breast and/or ovarian cancer, and in screening for mutations in *BRCA1*, *BRCA2*, and other candidate breast cancer susceptibility genes. This Core supports Projects 2 and 3 (as well as the other Project in the BCE if the need arises), by providing a highly accurate and cost-effective means for testing eligible participants for mutations in the two most prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*.

KEY RESEARCH ACCOMPLISHMENTS

- Improved the ability to detect *BRCA1* and *BRCA2* mutations in genomic DNA.
- Reduced the cost of full *BRCA1* and *BRCA2* mutation analyses to a third of the cost of commercial testing without loss of sensitivity.
- Created *BRCA1* and *BRCA2* exon chips for detection of genomic rearrangements in these two genes.
- Included mutation detection technology for large deletions/insertions in *BRCA1*, an extension of PCR based mutation detection.

REPORTABLE OUTCOMES

- Abstracts

*=supported by DAMD17-01-1-0238 ("Tailored Communications to Enhance Adaptation Across the breast Cancer Spectrum")

**=Demonstrates refinement and application of our methods to detect germline mutations in high-risk individuals.

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CONCLUSION

The work that we have preformed during the first two years of this application has served to improve our ability to detect mutations in the two prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*. We have published our mutation detection method and have shown that it is comparable if not superior to commercial methods at a significantly lower cost. We have also developed a method to detect large genomic rearrangements in *BRCA1* and *BRCA2* that elude detection when using PCR-based approaches to search for mutations. We have also included in our testing regimen a PCR based method for detecting large insertions/deletions in *BRCA1*. Overall, we are in optimal position to appropriately analyze any and all BCE samples once they become available through Projects 2 and 3. Furthermore, we will be able to process more samples than originally proposed due to our technical improvements and ability to automate the method.

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None

APPENDIX A

PROJECT 2: TAILORED PRINT MATERIALS

EXERCISE & DIET FACT SHEET

Most health experts agree that exercise at all ages is important for a healthy lifestyle. Research suggests that women who are physically active have a lower risk of breast cancer. Exercise also lowers rates of other cancers, osteoporosis and heart disease. Physical activity can include both sports activities and exercise you get at work or at home. The important thing is to choose something that you will enjoy and can continue on a regular basis.

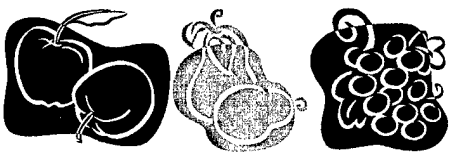
While most research has focused on the effect of exercise in preventing cancer, there is increasing evidence that exercise also influences other aspects of the cancer experience including detection, coping, and survival after diagnosis.

The amount of alcohol you drink is another important aspect of your lifestyle. Although small amounts of alcohol are thought to be healthy for your heart, regular use of large amounts of alcohol, like more than two glasses a day, have been shown to increase a woman's risk for breast cancer. It is thought that this is a result of alcohol converting certain hormones in the blood to forms of estrogen. Scientists know there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher your risk for breast cancer.

Another area of the diet receiving a lot of attention is soy intake. The amount of soy foods eaten in Asian countries is far higher than in the U.S., and that is thought to play a key role in the reduced risk of breast cancer in those countries. Soy foods contain isoflavones such as genistein, which had previously been thought to reduce the risk of breast cancer. However, some new studies have shown that consuming genistein may carry some risk of actually promoting certain types of breast cancer, especially those cancers that are estrogen dependent.

So how can one substance both prevent cancer and promote cancer at the same time? Researchers are still looking at this question but some think that genistein may have its greatest cancer-fighting effect in premenopausal women. For now, we know that foods containing isoflavones such as genistein have been eaten safely for centuries in many countries of the world. Until more is known, it seems prudent to use whole-soy foods as part of a healthy diet, because their health benefits—particularly for improving cholesterol levels and promoting heart health—are better established.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer. The program offers education, cancer risk assessment and evaluation of screening and prevention programs that may be appropriate for you. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area. For general information on breast cancer, nutrition, exercise or smoking cessation, please feel free to call the Cancer Information Service at 1-800-4-CANCER.



Teachable Moment Fact Sheets
Legend

Screening Recommendations Fact Sheets:

H/C-S= high monitor/compliant-start screening (used for women under age 40 who have not yet begun screening mammography)

H/C-C=high monitor/compliant-continue screening (used to reinforce continued compliance w/mammography)

H/N=high monitor/non-compliant

L/C-S=low monitor/complaint-start screening (same as H/C-S above)

L/C-C=low monitor/compliant-continue screening (same as H/C-C above)

L/N=low monitor/non-compliant

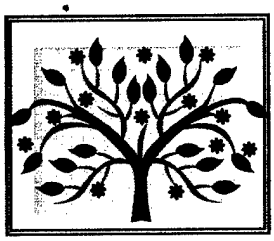
Family History/Risk Factors Fact Sheets:

H/H=high monitor/high risk

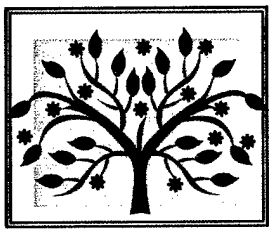
H/I=high monitor/intermediate risk

L/H=low monitor/high risk

L/I=low monitor/intermediate risk



Family History/Risk Factors Fact Sheet



There are several different factors that influence a woman's risk for developing breast cancer. One is age. Breast cancer is more common in older women than in younger women. It seems that most tissues, as they age, become more prone to genetic damage that can lead to cancer. So the longer a woman lives, the more likely she is to have a cell or cells in the breast tissue which can develop changes leading to cancer.

Another risk factor is family history. In families like yours, where there are multiple people diagnosed with breast cancer, other women in the family have a higher than average risk. In some cases, this may be explained by several women in the same family sharing common exposures or lifestyle factors. There is also the possibility that there is a genetic mutation being passed down through the family that greatly increases the risk of breast cancer.

Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. So if a parent carries one of these damaged genes, they have a 50% chance of passing it down to each of their children. Fortunately damaged genes like this are not common, but if a family does have one of these genes there are certain clues in the family history:

* If the breast cancers are occurring at very young ages, for instance less than 40;
* If there are multiple cases of breast cancer in one side of the family;
* If a woman gets breast cancer in both breasts;
* If there is also ovarian cancer in the family;
* Or if a man in the family gets breast cancer;

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Scientists think there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher your risk for breast cancer. This possibility was recently strengthened by a study that found that women who used hormone replacement therapy (which included both estrogen and progesterone) for menopause had a somewhat increased chance of developing breast cancer.

Having your first baby when you are young, say under 20, is protective. But never having children or having them after age 35 increases your risk. A pregnancy when you are young helps the cells in the breast become fully mature and therefore less likely to suffer genetic damage. If you never get pregnant, the cells remain somewhat immature and more vulnerable. If your first pregnancy is after age 35, apparently the cells have already sustained some genetic damage (from aging) and are more susceptible to the influence of the hormones related to the pregnancy.

The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

Please see the attached sheet for your personal risk profile.



The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA1/2* genes if it seems appropriate. If you decide you

Family History/Risk Factors Fact Sheet

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Another risk factor is family history. In families like yours, where there is already someone diagnosed with breast cancer, other women in the family have a higher than average risk. In some cases, this may be explained by several women in the same family sharing common exposures or lifestyle factors. There is also the possibility that there is a gene being passed down through the family that greatly increases the risk of breast cancer.

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* If the breast cancers are occurring at very young ages, for instance less than 40;
* If a woman gets breast cancer in both breasts;
* If there is also ovarian cancer in the family;
* Or if a man in the family gets breast cancer;

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Scientists think there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher your risk for breast cancer. This possibility was recently strengthened by a study that found that women who used hormone replacement therapy (which included both estrogen and progesterone) for menopause had a somewhat increased chance of developing breast cancer.

Having your first baby when you are young, say under 20, is protective. But never having children or having them after age 35 increases your risk. A pregnancy when you are young helps the cells in the breast become fully mature and therefore less likely to suffer genetic damage. If you never get pregnant, the cells remain somewhat immature and more vulnerable. If your first pregnancy is after age 35, apparently the cells have already sustained some genetic damage (just from aging) and are more susceptible to the influence of the hormones related to the pregnancy.

The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

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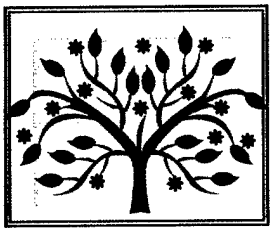
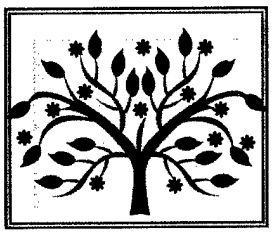


Family History/Risk Factors Fact Sheet



There are several different factors that influence a woman's risk for developing breast cancer:

1. Older age. Breast cancer is more common in older women than in younger women.

2. Family history. In families like yours, where there are multiple people diagnosed with breast cancer, other women in the family have a higher than average risk.

3. Genes. Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. Fortunately damaged genes like this are not common, but we can tell from certain clues in the family history if a family may have one of the mutations:

* Breast cancer occurs at very young ages, for instance less than 40;
* Multiple cases of breast cancer in the family;
* Breast cancer in both breasts;
* Ovarian cancer in the family;
* A man in the family with breast cancer;

4. Female Hormones. Scientists think there is a link between the hormones your body makes or hormones you are exposed to through food or medications (including estrogen and progesterone), and breast cancer. One such medication could be hormone replacement therapy for menopause.

5. Age at first pregnancy. Never having children or having them after age 35 increases your risk for breast cancer, but having your first baby when you are young, say under 20, is protective.

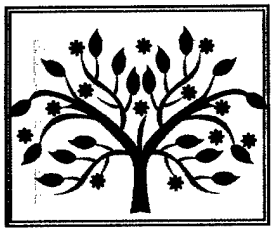
6. Breast biopsies. The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

Please see the attached sheet for your personal risk profile.

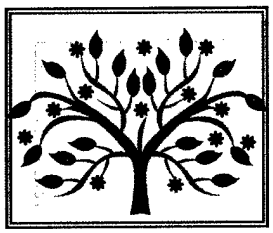


The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA1/2* genes if it seems appropriate. If you decide you would like to participate, you will also

L/H



Family History/Risk Factors Fact Sheet



There are several different factors that influence a woman's risk for developing breast cancer:

1. Older age. Breast cancer is more common in older women than in younger women.

2. Family history. In families like yours, where there is already someone diagnosed with breast cancer, other women in the family have a higher than average risk.

3. Genes. Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. Fortunately damaged genes like this are not common, but we can tell from certain clues in the family history if a family may have one of the mutations:

* Breast cancer occurs at very young ages, for instance less than 40;
* Breast cancer in both breasts;
* Ovarian cancer in the family;
* A man in the family with breast cancer;

4. Female Hormones. Scientists think there is a link between the hormones your body makes or hormones you are exposed to through food or medications (including estrogen and progesterone), and breast cancer. One such medication could be hormone replacement therapy for menopause.

5. Age at first pregnancy. Never having children or having them after age 35 increases your risk for breast cancer, but having your first baby when you are young, say under 20, is protective.

6. Breast biopsies. The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

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Screening Recommendations Fact Sheet

Current recommendations for screening and prevention of breast cancer work toward the goal of finding cancers when they are at an early, and more curable stage. The earlier a cancer is found and removed, the lower the risk of it spreading to other parts of the body. Therefore, it is very important for you to continue a regimen of breast cancer screenings.

There are three different ways to detect early stage breast cancer. We generally urge women to examine their own breasts for unusual lumps or skin changes on a monthly basis, starting in their 20's. Once you get used to what your breast tissue feels like, you may be able to detect an area that feels different than the usual tissue. You can also see subtle changes in the skin of the breast like dimpling or redness that should be brought to the attention of a health care provider.

A clinical breast exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse examines the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin.

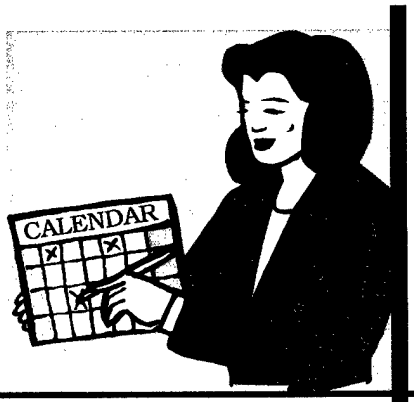
The American Cancer Society recommends that all women begin annual mammography starting at age 40. Women with a family history of breast cancer may need to start screening with annual mammograms at an earlier age. This is something you could discuss with your doctor or with a cancer risk counselor. Mammograms can detect lumps that are less than the size of a pea. They can also detect areas of abnormal calcium deposits, even before any lump can be seen.

No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography combined can find breast cancer at an early stage.

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen, approved for prevention in women with certain risk factors. Tamoxifen blocks estrogen from entering the glandular cells in the breast, and therefore can protect those cells from estrogen stimulation. Tamoxifen has now been shown to reduce the risk of getting breast cancer in women with a high risk by 50 percent.

Based on your age and family history, we would recommend you continue with annual mammograms as you are already doing.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.



H/C-C

Screening Recommendations Fact Sheet

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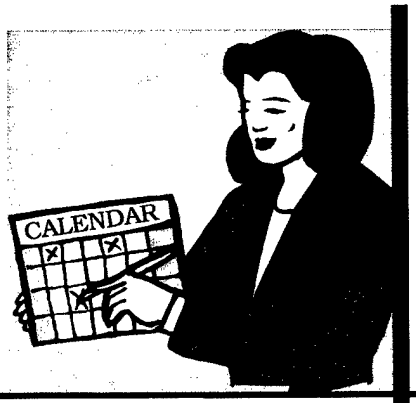
Based on your age and your family history, we would recommend starting annual mammograms at age _____.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.



Screening Recommendations Fact Sheet

Current recommendations for screening and prevention of breast cancer work toward the goal of finding cancers when they are at an early, and more curable stage. The earlier a cancer is found and removed, the lower the risk of it spreading to other parts of the body. Therefore, it is important to begin a screening routine today.

There are three different ways to detect early stage breast cancer. We generally urge women to examine their own breasts for unusual lumps or skin changes on a monthly basis, starting in their 20's. Once you get used to what your breast tissue feels like, you may be able to detect an area that feels different than the usual tissue. You can also see subtle changes in the skin of the breast like dimpling or redness that should be brought to the attention of a health care provider.

A clinical breast exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse examines the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin.

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Another option for women at increased risk for breast cancer is taking the drug Tamoxifen, which has been approved for prevention in women with certain breast cancer risk factors. Tamoxifen blocks estrogen from entering the glandular cells in the breast, and therefore can protect those cells from estrogen stimulation. Tamoxifen has been shown to reduce the risk of getting breast cancer in women with a high risk by 50 percent.

Based on your age and your family history, we would recommend getting on schedule with your annual mammogram, which is overdue.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

H/N

Screening Recommendations Fact Sheet

Screening for breast cancer is recommended because it may find cancers when they are at an early, and more curable stage. That's why it is important to continue a routine of exams and mammograms.

There are three different ways to detect early stage breast cancer:

1. Breast Self Exam (BSE) Women should examine their breasts on a monthly basis for changes in the breast tissue such as unusual lumps or dimpling of the skin.

2. Clinical Breast Exam This exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse examines the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin.

3. Mammograms The American Cancer Society recommends that all women begin annual mammography starting at age 40. Women with a family history of breast cancer may need to start annual mammograms at an earlier age.

No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography combined can find a breast cancer at an early stage.

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen. Tamoxifen has been shown to reduce the risk of getting breast cancer in high risk women by half.

Based on your age and your family history, we would recommend continuing with annual mammograms as you are already doing.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

L/C-C

Screening Recommendations Fact Sheet

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No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography combined can find a breast cancer at an early stage.

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen. Tamoxifen has been shown to reduce the risk of getting breast cancer in high risk women by half.

Based on your age and your family history, we would recommend starting annual mammograms at age_____.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

L/C-S

Screening Recommendations Fact Sheet

Screening for breast cancer is recommended because it may find cancers when they are at an early, and more curable stage. That's why it is important to begin a routine of exams and mammograms and follow it throughout the year.

There are three different ways to detect early stage breast cancer:

1. Breast Self Exam (BSE) Women should examine their breasts on a monthly basis for changes in the breast tissue such as unusual lumps or dimpling of the skin.

2. Clinical Breast Exam This exam is given by a health care professional, usually once or twice a year during a routine gynecologic or physical exam. A physician or nurse examines the breasts for abnormal lumps and other changes in the shape of the breast or skin.

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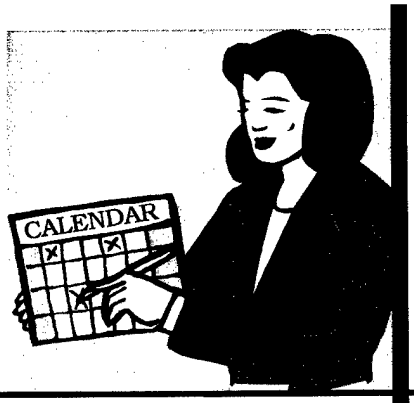

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PERSONAL RISK PROFILE for

_____

As we discussed during the telephone counseling session, the Gail model tries to put your risk factors together to give you five-year and lifetime risk estimates for developing breast cancer. Based on the information you provided to us, your personal risk factors for breast cancer include:

☐ **age 50 or over**

☐ **young age (before age 12) when your periods started**

☐ **not having children**

or

☐ **having your first child after age 35**

☐ **having _____ first-degree relative(s) with breast cancer**

☐ **having _____ breast biopsies**

Considered together, based on the Gail model, we calculate your risk as follows:

5-year risk

Based on the data provided your estimated risk for invasive breast cancer over the next 5 years is _____%, compared over the same period to that of _____% for a woman of your age with average risk factors.

This also means that your estimated risk for NOT getting invasive breast cancer over the next 5 years is _____%.

Lifetime risk

Your lifetime risk (to age 90) for invasive breast cancer is _____%. A woman of your age with average risk factors would have an estimated risk of invasive breast cancer of _____%. This also means that your estimated risk for NOT getting invasive breast cancer in your lifetime is_____%.

PERSONAL RISK PROFILE for

_____

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This also means that your estimated risk for NOT getting invasive breast cancer over the next 5 years is _____%.

Your 5 year risk is sufficient to consider discussing with your doctor the use of tamoxifen to help prevent breast cancer. Tamoxifen has been shown to reduce the risk of getting breast cancer in women at high risk by 50%.

Lifetime risk

Your lifetime risk (to age 90) for invasive breast cancer is _____%. A woman of your age with average risk factors would have an estimated risk of invasive breast cancer of _____%. This also means that your estimated risk for NOT getting invasive breast cancer in your lifetime is_____%.